VASCULAR-ACCESS SIMULATION SYSTEM WITH RECEIVER FOR AN END EFFECTOR

Statement of Related Cases

[0001] This case is related to U.S. Patent Applications S.N. _____ (Atty. Dkt. No. 115-001), S.N. _____ (Atty. Dkt. No. 115-003), S.N. _____ (Atty. Dkt. No. 115-004), and S.N. _____ (Atty. Dkt. No. 115-005), all of which are incorporated by reference herein.

Field of the Invention

[0002] The present invention relates generally to systems that simulate medical procedures for the purposes of training or accreditation. More particularly, the present invention relates to a system, apparatus and subsystems for simulating vascular-access procedures.

Background of the Invention

[0003] Medical practitioners, such as military medics, civilian emergency-medical personnel, nurses, and physicians, routinely perform vascular-access procedures (*e.g.*, IV insertion, central venous-line placement, peripherally-inserted central catheter, *etc*). It is desirable for a practitioner to be proficient at performing these procedures since the proficient practitioner is far less likely to injure a patient and is almost certain to reduce the patient's level of discomfort.

[0004] Becoming proficient in vascular-access procedures requires practice. In fact, the certification and re-certification requirements of some states mandate a minimal number of needle sticks, *etc.*, per year per provider. Historically, medical practitioners practiced needle-based procedures on live volunteers. More recently, simulation techniques and devices have been developed to provide training in vascular-access procedures without the use of live volunteers. U.S. Pat. No. 6,470,302 ("the '302 patent") surveys the art of medical-simulation devices and also discloses a vascular-access simulation system.

[0005] The vascular-access simulation system that is disclosed in the '302 patent includes an "interface" device and a computer system. To practice a vascular-access procedure, a user manipulates an "instrument," referred to in the patent as a "catheter unit assembly," which extends from the device and serves as a catheter-needle. Potentiometers and encoders within the interface device track the

motion and position of the instrument and relay this information to the computer system. The computer system performs a simulation of the surface and subsurface anatomy of human skin, and determines the effect of the instrument's motion on the skin's anatomy. Simulated results are displayed by the computer system. Using the motion information from the interface device, the computer system also generates a control signal that controls a force-feedback system that is coupled to the instrument. The force-feedback system generates various resistive or reactive forces that are intended to simulate the forces that are experienced by a medical practitioner during an actual vascular-access procedure. The user senses these forces during manipulation of the instrument.

[0006] The simulation system that is disclosed in the '302 patent has many shortcomings that substantially limit its utility as a training or accreditation tool. A few of these shortcomings are discussed below.

[0007] One shortcoming of that simulation system is that forces that are sensed by a user during manipulation of the catheter unit assembly are generally unrealistic. There are several reasons for this. One reason is that the linear axis along which the catheter unit assembly moves is offset from the rotational axes of a sensing/force-feedback assembly to which it's coupled. This results in an unrealistic torque sensation about the "insertion point" of the catheter unit assembly. A second reason for the unrealistic forces and force sensations that are experienced by a user is excessive friction. Specifically, the various tension members and bearings that couple the catheter unit assembly to the sensing/force-feedback assembly introduce a substantial amount of dynamic and static friction to the system. This is problematic because the interface device cannot present a force that is less than the friction that is inherent in the system. This excessive friction therefore limits the dynamic range of the system. Also, the presence of static friction (*i.e.*, stiction) in the device hampers smooth motion of the catheter unit assembly. Stiction is not experienced during an actual vascular-access procedure.

[0008] A third reason for the unrealistic forces that are experienced during use of the device that is disclosed in the '302 patent is that the device has relatively high inertia. In particular, the large catheter unit assembly and the offset pulley used in the force-feedback mechanism introduce substantial mass into the system. This is undesirable because the catheter unit assembly will not feel as "light" as it should when little or no force feedback is being applied.

[0009] A second shortcoming of the '302 is that the end effector (*i.e.*, the catheter unit assembly) is permanently coupled to the force-feedback system. Although not atypical for this type of system (*i.e.*, haptics devices) due to the difficulty of de-coupling an end effector from its force-feedback system, this is very undesirable because to truly mimic most "actual" systems, de-coupling is necessary.

[0010] For example, in the case of an actual vascular-access procedure, a medical practitioner experiences "force-feedback" during insertion of a needle or catheter (*i.e.*, an end effector) into a patient's arm. That is, the anatomy of the arm presents a resistance that is sensed (feedback) by the practitioner. In the actual procedure, the needle or catheter is not, of course, "coupled" to the arm *until* it is inserted by the practitioner. But in the system that is disclosed in the '302 patent, the catheter unit assembly is coupled to the force-feedback system and extends from interface device *at all times*. A user, therefore, does not actually *insert* the catheter unit assembly (*i.e.*, the end effector); there is no coupling and de-coupling.

[0011] The inability of prior-art vascular-access simulation systems to realistically simulate a vascular-access procedure limits their usefulness as a training or accreditation tool.

Summary

[0012] The illustrative embodiment of the present invention is a simulation system that provides realistic training and practice for performing vascular-access procedures without using human subjects. Unlike most prior-art simulation systems, some embodiments of the present system provide a realistic simulation of the resistive forces that a medical practitioner would experience if the simulated procedure were an actual procedure that was being performed on a real anatomy (*e.g.*, human arm, *etc.*). Furthermore, in accordance with the illustrative embodiment of the present invention, the end effector (*e.g.*, medical instrument, such as a needle, catheter, *etc.*) is not coupled to a force-feedback system until a user does so.

[0013] The illustrative embodiment of a vascular-access simulator includes a data-processing system and an interface device, referred to herein as a "haptics device." The haptics device provides the physical interface for performing vascular-access procedures. More particularly, a user inserts an end effector into the haptics device and manipulates it to simulate needle insertion, cannulation, *etc.* In some

embodiments, the simulator is capable of sensing the orientation of the end effector. For example, in some embodiments in which the end effector is a needle or catheter or both, the simulator is capable of sensing the orientation of a beveled end of the needle or catheter.

[0014] In accordance with the illustrative embodiment, the haptics device includes a receiver that receives the end effector when it is inserted into the haptics device. In some embodiments in which the end effector is a needle-catheter module, the receiver is a needle-stick module.

[0015] In some embodiments, the needle-stick module provides one linear degree of freedom and two, independent, rotational degrees of freedom (*i.e.*, pitch and yaw). In the illustrative embodiment, the linear degree of freedom enables a user to advance the needle/catheter module into the haptics device. This mimics the insertion of a needle/catheter into a patient's arm. The rotational degrees of freedom enable a user to move an engaged needle/catheter module up or down and left or right. This mimics the freedom of movement that a user has during an actual vascular-access procedure.

[0016] Sensors within the haptics device monitor the motion and position of the needle/catheter module (*e.g.*, by measuring the insertion depth and pitch and yaw angles of the needle-stick module, *etc.*). The sensors generate signals indicative of the monitored activity and transmit the signals to the data processing system.

[0017] The data processing system processes the information acquired by the sensors and, in conjunction with an anatomical model, determines the effects (*e.g.*, deformation, entry into a vein, *etc.*) of a user's manipulation of the needle/catheter module on the surface and subsurface features of the virtual body part on which the simulated vascular-access procedure is being performed. Results are displayed by the computer system. The results include, for example, a three-dimensional rendering of the body part of interest, a visual indication of the position of the needle/catheter relative to the body part, and a visual indication of how the needle/catheter affects that body part.

[0018] Furthermore, in some embodiments, using the anatomical model and the information obtained from the sensors, the data processing system determines the various resistive forces that would arise if the user were manipulating a needle or catheter through an actual anatomy (*e.g.*, human arm, *etc.*). Based on this

determination, the data processing system or an associated device generates a control signal.

[0019] The control signal is ultimately received by the needle-stick module and, responsive thereto, the needle-stick module provides "force feedback" to a user. The force-feedback is sensed by a user as a resistance to continued advance (insertion) of the needle/catheter module. The resistance is intended to simulate penetration or contact with various surface and subsurface features of human anatomy (*e.g.*, the skin, a vein, harder structures such as ligaments, bones, *etc.*) The resistance advantageously varies with insertion depth and the pitch and yaw of the needle/catheter module (since the resistance is determined based on the estimated position of needle/catheter module in a portion of the human anatomy).

[0020] As previously mentioned, it is typical, although undesirable, for an end effector to be permanently coupled to a force-feedback system. In accordance with the illustrative embodiment of the present invention, the needle/catheter module (*i.e.*, an end effector) is not coupled to the needle-stick module (which includes a force-feedback assembly) until a user couples them during a simulated vascular-access procedure. And when the simulated procedure is over, the user decouples the needle/catheter module from the needle-stick module. A user's interactions with simulators described herein therefore more closely simulate a real vascular-access procedure than simulators in the prior art. This more realistic simulation is expected to result in a more useful training experience.

Brief Description of the Drawings

[0021] **FIG. 1** depicts vascular-access simulation system **100** in accordance with the illustrative embodiment of the present invention.

[0022] **FIG. 2** depicts functional elements of haptics device **102**, which is a part of vascular-access simulation system **100**.

[0023] **FIG. 3** depicts a top view of haptics device **102**.

[0024] **FIG. 4A** depicts the salient elements of vascular-access simulation system **100**, wherein the end effector is not yet inserted into a receiver within haptics device **102**.

[0025] **FIG. 4B** depicts vascular-access simulation system **100** showing the end effector coupled to the receiver within haptics device **102**.

[0026] **FIG. 5** depicts an illustrative embodiment of the needle/catheter module.

[0027] **FIG. 6** depicts the pseudo needle of the module depicted in FIG. 5.

[0028] **FIG. 7** depicts the pseudo catheter of the module depicted in FIG. 5.

[0029] **FIG. 8** depicts an embodiment of vascular-access simulation system **100** wherein said system includes a data processing system, pseudo skin, an end effector, and a receiver having a sensor and a force-feedback system.

[0030] **FIG. 9** depicts the needle/catheter module coupled to a movable member in the receiver.

[0031] **FIGs. 10A – 10C** depict an illustrative embodiment of the needle-stick module, including a receiving module.

[0032] **FIGs. 11A – 11D** depict further detail of the receiving module.

[0033] **FIG. 12** depicts an embodiment of the movable member.

Detailed Description

[0034] The terms and phrases listed below are defined for use in this specification as follows:

[0035] "**End Effector**" means a device, tool or instrument for performing a task. The structure of an end effector depends on the intended task. For example, in the illustrative embodiment, the end effector is intended to be used to simulate a vascular access procedure, and is therefore implemented as a catheter-needle module. Those skilled in the art will recognize that term "end effector" is borrowed from robotics, where it has a somewhat different definition: a device or tool connected to the end of a robot arm.

[0036] "**Imitation**" means an artificial likeness that is intended to be substantially similar to an item being imitated; a copy. For example, "imitation skin," which is used in conjunction with the illustrative embodiment of the present invention, is intended to mimic or copy genuine skin via appropriate selection of color, appearance, feel, and overall presentation.

[0037] "**Mock**" means "representative;" a stand-in for a genuine article, but not intended to closely imitate the genuine article. A mock article will never be confused with the genuine article and typically does not promote a suspension of

disbelief that the mock article is the genuine article. For example, "mock skin" is not intended to mimic genuine skin, and typically departs from it in terms of color, appearance, feel or overall presentation.

[0038] "**Pseudo**" is an inclusive term that means "imitation" or "mock." For example, pseudo skin is meant to encompass both imitation skin and mock skin.

[0039] "**Skin**" means genuine skin.

[0040] Additional definitions are provided later in this Detailed Description.

[0041] This *Detailed Description* continues with an overview of a vascular-access simulator in accordance with the illustrative embodiment. Following the overview, specific embodiments of several elements of the simulator are described in greater detail.

Overview

[0042] The illustrative embodiment of the present invention pertains to a simulation system that provides realistic training and practice for vascular-access procedures without using human subjects. As depicted in FIG. 1, vascular-access simulator **100** includes haptics device **102** and data-processing system **104**.

[0043] Haptics device **102** provides the physical interface for performing any of several simulated vascular-access procedures (*e.g.*, intravenous catherization, central venous-line placement, sternal intraosseous insertion, *etc.*).

[0044] The term "haptics" (as in "haptics device **102**") relates to touch (*i.e.*, the sense of touch). A fundamental function of haptics device **102**, and indeed any haptics interface, is to create a means for communication between users (*i.e.*, humans) and machines. This "communication" is possible since humans are capable of "mechanically" interfacing with their surroundings due, at least in part, to a sense of touch. This "sense of touch" includes sensations of pressure, texture, puncture, thermal properties, softness, wetness, friction-induced phenomena, adhesions, *etc.* Furthermore, humans also experience vibro-tactile sensations, which include the perception of oscillating objects in contact with the skin and kinesthetic perceptions (*i.e.*, awareness of one's body state, including position, velocity, and forces supplied by the muscles). As will become clear later in this *Detailed Description*, our ability to perceive a variety of these sensations is exploited by haptics device **102**.

[0045] To the extent that some embodiments of simulator **100** are intended for use as a practice and training tool, it is advantageous for haptics device **102** to simulate vascular-access procedures as realistically as possible and provide a quantitative measure of the user's performance of the simulated procedure. To this end, haptics device **102** possesses one or more of the following attributes, in addition to any others:

- It possesses sufficient degrees-of-freedom to simulate the relatively free movement of a needle/catheter during an actual vascular-access procedure.
- It offers the opportunity to perform all steps of a vascular-access procedure, including, for example, needle insertion, skin interactions (*e.g.*, palpation, skin stretch, *etc.*), catheter threading, *etc.*
- It generates appropriate skin- and venous-puncture forces.
- It measures or otherwise quantifies the effects of user actions on simulated anatomy.
- It generates appropriate haptic feedback (*i.e.*, feel) during skin-interaction steps.
- It is configured to provide ergonomically-correct hand position during simulated vascular-access procedures.
- It is small enough so that it can be positioned in front of a computer monitor so that the haptics device and the monitor are inline with a user's forward-looking field of view.
- It is at least subtly suggestive of human anatomy and does not present any substantial departures therefrom so as to support a user's ability to suspend disbelief during a simulated vascular-access procedure.

[0046] Data-processing system **104**, which includes processor **106**, monitor **108**, keyboard **110**, mouse **112**, and speakers **114**, supports the visual aspects of the simulation and other functions described below. Processor **106** is a general-purpose processor that is capable of receiving and processing signals from haptics device **102**, running software for the visual portion of the vascular-access simulation including an anatomy simulator, running calibration software for calibrating the various sensing elements used in haptics device **102**, and sending control signals to haptics device **102** to support closed-loop force feedback, among other capabilities.

Processor **106** comprises memory, in which the software described above is stored. In the illustrative embodiment, processor **106** is a personal computer.

[0047] Monitor **108** displays a rendering that is generated by processor **106**, in conjunction with the above-referenced software. The rendering, which in some embodiments is three-dimensional, is of a region of the body (*e.g.*, isolated arm, thorax, neck, *etc.*) on which a simulated vascular-access procedure is being performed. The rendering advantageously depicts visual aspects such as, without limitation, the anatomical structures that underlie skin, local deformation of the skin in response to simulated contact, and tracking of a "virtual" instrument (*e.g.*, a needle, *etc.*) through anatomical structures that underlie the skin.

[0048] Haptics device **102** is now described in further detail. For pedagogical purposes, haptics device **102** is depicted in FIG. 2 as comprising several functional modules or elements. These include:

- End effector or Needle/catheter module **218**;
- Pseudo skin **220**;
- Palpation module **222**;
- Skin-stretch module **224**;
- Receiver or Needle-stick module **226**; and
- Electronics/communications interface **228**.

[0049] The functional elements of haptics device **102** listed above that relate to human anatomical features or are otherwise intended to generate resistive forces that would be sensed when penetrating such anatomical features (elements **222** – **228**) are advantageously contained within housing **216** or otherwise located "underneath" pseudo skin **220**. In an actual vascular-access procedure, the needle or catheter, of course, remains outside of the body until inserted during the procedure. Likewise, in accordance with the illustrative embodiment, the end effector—needle/catheter module **218**—remains outside of housing **216** and pseudo skin **220** until a portion of it is inserted during a simulated vascular-access procedure. In some embodiments, housing **216** is subtly shaped like a portion of a human arm, yet is nondescript enough to avoid creating a discontinuity between what is seen and what is felt.

[0050] Pseudo skin **220** is a membrane that is used in conjunction with the simulation of skin-interaction techniques, such as palpation, occlusion, and skin stretch techniques. Pseudo skin **220** is advantageously, but not necessarily,

imitation skin (*i.e.*, skin-like in appearance). In embodiments in which pseudo skin **220** is imitation skin, it possesses any one of a number of natural flesh tones. In some embodiments, pseudo skin **220** is at least somewhat resilient to enable a user to perform skin-interaction techniques. In some embodiments, pseudo skin **220** comprises a thermoplastic elastomer such as Cawiton®, which is available from Wittenburg, B.V., Hoevelaken, Netherlands. The use of imitation skin, as opposed to mock skin, is desirable because it helps a user to "suspend disbelief," which contributes to making simulator **100** more useful as a training tool.

[0051] As depicted in FIG. 3, pseudo skin **220** is accessed for insertion and skin-interaction techniques (*e.g.*, palpation, occlusion, skin stretch, *etc.*) through openings **330** and **332** in housing **216**. Opening **330** defines palpation/occlusion region **331** (*i.e.*, the site at which palpation and occlusion techniques are performed) and opening **332** defines skin-stretch region **333** (*i.e.*, the site at which the skin-stretch technique is performed) and includes insertion point **334** for the end effector (*e.g.*, needle/catheter module **218**).

[0052] The ability to perform skin-interaction techniques provides a more realistic simulation of vascular-access procedures. In some embodiments, this ability is provided in conjunction with palpation module **222** and skin-stretch module **224**. These modules, and illustrative embodiments thereof, are described in further detail applicant's co-pending U.S. Patent Application S.N. _____ (Atty. Dkt. 115-001).

[0053] Pseudo skin **220** is disposed adjacent to the inside surface of housing **216** so that it appears to be nearly co-extensive (*i.e.*, co-planar) with housing **216** at openings **330** and **332**. This is intended to create a subtle suggestion that the surface of housing **216** is "skin" at regions other than where pseudo-skin **220** is accessed for skin-interaction techniques. Consistent with human anatomy, the remaining functional elements of haptics device **102** (elements **222** – **228**), with the exception of needle/catheter module **218**, are "hidden" beneath pseudo skin **220**.

[0054] The end effector (*e.g.*, needle/catheter module **218**, *etc.*) is inserted into haptics device **102** at insertion point **334** in opening **332**. In some embodiments, simulator **100** is capable of sensing orientation of the end effector, such as to determine the orientation of a feature of a needle or catheter. In some embodiments, the feature is a bevel. This is an important aspect of the real insertion technique, since proper bevel orientation reduces a patient's discomfort

during needle/catheter insertion. In some embodiments, needle/catheter module **218** is configured to be very similar to a real needle and catheter.

[0055] Once inserted into haptics device **102**, the tip of needle/catheter module **218** engages receiver **226**, which, for the illustrative embodiment of a vascular access simulator, is referred to as a "needle-stick module." Needle-stick module **226** supports the continued "insertion" of the needle/catheter module **218**. In particular, in some embodiments, needle-stick module **226** is configured to provide one linear degree of freedom and two rotational degrees of freedom (*i.e.*, pitch and yaw). The linear degree of freedom provides a variable insertion depth, enabling a user to advance needle/catheter module **218** into the "patient's arm" (*i.e.*, haptics device **102**). The rotational degrees of freedom enable a user to move (an engaged) needle/catheter module **218** up or down and left or right. In some embodiments, needle-stick module **226** measures insertion depth, and pitch (up/down) and yaw (left/right) angles.

[0056] In some embodiments, needle-stick module **226** provides "force feedback" to a user, whereby the user senses a variable resistance during continued advance (insertion) of needle/catheter module **218**. The resistance is intended to simulate penetration of the skin, a vein, and harder structures such as ligaments, bones, and the like. The resistance advantageously varies with insertion depth and the pitch and yaw of needle/catheter module **218**, as described further below.

[0057] It will be understood that the "measurements" of angle, position, *etc.* that are obtained by the functional elements described above are obtained in conjunction with various sensors and data-processing system **104**. In particular, most of the functional elements described above include one or more sensors. The sensors obtain readings from an associated functional element, wherein the readings are indicative of the rotation, displacement, *etc.*, of some portion of the functional element. These readings provide, therefore, information concerning the manipulation of needle/catheter module **218** in addition to any parameters.

[0058] Each sensor generates a signal that is indicative of the reading, and transmits the signal to electronics/communications interface **228**. Sensors used in some embodiments include, without limitation, potentiometers, encoders, and MEMS devices. Those skilled in the art will know how to use and appropriately select sensors as a function of their intended use in conjunction with the functional elements described above.

[0059] Electronics/communications interface **228** receives the signals transmitted by the various functional elements of haptics device **102** and transmits them, or other signals based on the original signals, to data-processing system **104**. Furthermore, electronics/communications interface **228** distributes power to the various functional modules, as required.

[0060] As described later below, electronics/communications interface **228** also receives signals from data processing system **104** and transmits them to needle-stick module **226**, among any other modules within haptics device **102**, as part of a closed loop force-feedback system. In some embodiments, the signals received from data processing system **104** are amplified before they are transmitted to needle-stick module **226**, *etc.* As an alternative to having electronics/communications interface **228** transmit the signals that are received from data processing system **104**, in some embodiments, the electronics/communications interface generates new signals based on the received signals. This approach, which is typically referred to as embedded control, is well known in the art. It disadvantageously requires a substantial increase in processing power and data management (relative to simply transmitting the received signals, or simply amplifying the received signals) and is generally a less-preferred approach.

[0061] Data-processing system **104** receives the measurement data and, using the simulation software, calculates the forces that are being applied by the user during the skin-interaction procedures. Furthermore, using an anatomical model, data-processing system **104** calculates the position and angle of a virtual needle within a simulated anatomy (*e.g.*, arm, *etc.*). Data-processing system **104** displays, on monitor **108**, a rendering of the appropriate anatomy (*e.g.*, arm, *etc.*) and displays and tracks the course of a virtual needle within this anatomy.

[0062] Furthermore, based on the position and course of the virtual needle (as calculated based on the position and orientation of needle/catheter module **218**), data-processing system **104** generates control signals that are transmitted to needle-stick module **226**. These control signals vary the resistive force presented by needle-stick module **226** to account for various anatomical structures (*e.g.*, vein, tissue, tendons, bone, *etc.*) that needle/catheter module **218** encounters, based on the simulation. As a consequence, the resistance to continued needle/catheter insertion that is experienced by a user of simulator **100** is consistent with the

resistance that would be sensed by a practitioner during an actual vascular access procedure.

[0063] Having completed the overview of vascular-access simulator **100** and haptics device **102**, the end effector (in the illustrative embodiment needle/catheter module **218**) and receiver (in the illustrative embodiment needle-stick module **226**) will be described in further detail.

[0064] FIGs. 4A and 4B depict haptics device **102** and data processing system **104** of simulator **100**. In the embodiment depicted in these Figures, haptics device **102** includes needle/catheter module **218**, needle-stick module **226** and electronics/communications interface **228**. It will be appreciated that in other embodiments, other functional modules (such as those described previously) in addition to or instead of needle-stick module **226** and electronics/communications interface **228** are typically present within haptics device **102**.

[0065] The needle-stick module and the electronics/communications interface are disposed within housing **216**. Both needle/catheter module **218** and needle-stick module **226** are electronically coupled to electronics/communications interface **228**, and through it coupled to data processing system **104**. As previously described, electronics/communications interface **228** provides power to these and other modules, receives signals from these and other modules as well as data processing system **104**, and sends signals to needle-stick module **226** and data processing system **104**.

[0066] Needle-stick module **226** is disposed substantially beneath pseudo skin **220** and is accessible to needle/catheter module **218** via insertion point **334**. In some embodiments, a portion (*i.e.*, guide **1089**, *see* ¶0086 and FIGs. 10A-10C) of needle-stick module **226** is raised slightly above the plane of pseudo skin **220** to simply the process of engaging needle/catheter module **218** to the needle-stick module. In the illustrative embodiment, insertion point **334** is an opening in pseudo skin **220**. In some other embodiments, the needle/catheter module penetrates pseudo skin **220**. FIG. 4A depicts the simulator before a user has inserted needle/catheter module **218** into needle-stick module **226**. FIG. 4B depicts the simulator after a user has inserted the needle/catheter module into the needle-stick module.

[0067] FIGs. 5-7 depict an illustrative embodiment of needle/catheter module **218** and its constituent parts. In the illustrative embodiment, needle/catheter

module includes needle portion **536** and catheter portion **554**, which can be coupled to or decoupled from one another. FIG. 5 depicts the needle portion and catheter portion coupled to one another. FIG. 6 depicts only needle portion **536** and FIG. 7 depicts only catheter portion **554**. When needle portion **536** is coupled to catheter portion **554**, needle **650** (FIG. 6) is received by catheter **758** (FIG. 7).

[0068] As depicted in FIG. 5, needle/catheter module **218** includes sensor **538**. In the illustrative embodiment, sensor **538** is disposed in needle portion **536**. In some embodiments, sensor **538** provides data that is indicative of the orientation of the bevel, such as bevel **760** of catheter portion **554** (*see*, FIG. 7). Those skilled in the art will know how to select and use a device to function as sensor **538**. In some embodiments, sensor **538** is one or more micro-electromechanical system (MEMS) devices. As is well known in the art, MEMS devices typically have a size within a range of about 100 nanometers to a millimeter, and are created using surface micro-machining techniques (*e.g.*, depositing mechanical and sacrificial layers, selectively etching to pattern, *etc.*)

[0069] In the illustrative embodiment that is depicted in FIG. 6, needle portion **536** includes needle housing **640**, needle **650**, and wire **652**. Housing **640** includes surface features such as ergonomic grip **642** and ridge **644**. Needle portion **536** and catheter portion **554** are configured for locking engagement, such as by inserting ridge **644** into a complementary slot (not depicted) in coupler **756** of catheter **554**.

[0070] Needle housing **640** contains sensor **538**, which in the illustrative embodiment depicted in FIG. 6 comprises two MEMS accelerometers **646** and **648**. The accelerometers are electrically coupled to wire **652**, which is, in turn, coupled to electrical/communications interface **228**. The accelerometers are oriented orthogonal to one another so that they detect motion along orthogonal axes. Each of accelerometers **646** and **648** is capable of generating a signal that is indicative of motion along two orthogonal axes. It is notable that while MEMS accelerometers **646** and **648** can detect motion along two orthogonal axes, this is not necessary for resolving the orientation of, for example, the bevel. This can be done by detecting motion along only one axis. This information obtained by the accelerometers is ultimately transmitted to data processing system **104** and used by it to resolve the orientation of housing **640** or anything rigidly coupled to it (such as catheter portion **554**) in two dimensions. MEMS accelerometers suitable for use as sensor **538**

include, for example, dual-axis accelerometers with duty cycle output, such as model ADXL202E available from Analog Devices, Inc. of Norwood, Massachusetts.

[0071] In the illustrative embodiment, needle portion **536** is connected via wire to electrical/communications interface **228**. But in some other embodiments, needle-catheter module **218** is a wireless device. In these other embodiments, needle portion **536** communicates wirelessly with either electrical/communications interface **228** or (directly) with data processing system **104**. In such embodiments, needle portion **536**, electrical/communications interface **228**, and data processing system **104** include a transceiver, receiver, or transmitter, as appropriate. In embodiments in which needle/catheter module **218** operates wirelessly, it advantageously includes its own power source, such as one or more lithium-ion batteries, *etc*. Those skilled in the art will know how to make and use embodiments of the present invention in which needle/catheter module **218** is configured for wireless operation.

[0072] In the illustrative embodiment, bevel **760** is formed on catheter **758**. Those skilled in the art of vascular-access techniques will recognize that in an authentic instrument (*i.e.*, authentic needle and catheter) the bevel is typically formed in the needle rather than the catheter. Bevel **760** is formed on catheter **758**, rather than needle **650**, as a preferred location in view of other design decisions (in particular, the manner in which needle **650** is coupled to needle-stick module **226**, which is described in detail later in this specification). In other embodiments, the bevel is formed on needle **650**. In such other embodiments, it will be advantageous to suitably modify the way in which needle **650** couples to needle-stick module **226**.

[0073] FIG. 8 depicts further detail of an illustrative embodiment of needle-stick module **226**. In this embodiment, needle-stick module includes force-feedback assembly **862** and sensor **864**. In FIG. 8, needle **650** or catheter **758** is shown "penetrating" pseudo skin **220** at insertion point **334** and is received by needle-stick module **226**.

[0074] Sensor **864**, which can be one or more sensors, senses the position of needle **650**/catheter **758**. In some embodiments, sensor(s) **864** obtains information indicative of the extent of penetration of the needle/catheter into needle-stick module **226**. In some other embodiments, sensor(s) **864** also measures the orientation of the needle/catheter, assuming that needle/catheter module **218** is free

to move in other directions. In other words, sensor(s) **864** monitor movement along axes that align with one or more available degrees of freedom.

[0075] Sensor(s) **864** generates signal(s) indicative of the monitored movement. The sensor(s) are directly or indirectly coupled to data processing system **104**. The signals, or other signals derived therefrom, are transmitted from sensor(s) **864** and are ultimately received by data processing system **104**. Using the data contained in the signal(s), and in conjunction with anatomical model **866** and force-calculation software **868**, the data processing system:

- determines the anatomical features that the needle/catheter would encounter (skin, vein, ligaments, bone, *etc.*), based on its position, were it moving through an actual anatomy; and
- calculates the resistive forces that would arise as the needle/catheter encounters these various anatomical features.

[0076] A control signal(s) is generated by controller **870** based on the force calculations. The control signal(s) is transmitted to haptics device **102** and is ultimately received by force-feedback assembly **862**.

[0077] Responsive to the control signal(s), force-feedback assembly **862** generates force F_R that opposes movement of the needle/catheter. In some embodiments, force F_R only opposes "forward" movement (*i.e.*, movement in the direction of continued insertion) of the needle/catheter through needle-stick module **226**. In some other embodiments, forces are generated that oppose movement of the needle/catheter both in the forward and reverse direction (*i.e.*, insertion and removal).

[0078] FIG. 9 depicts further detail of an embodiment of needle-stick module **226**. In the embodiment that is depicted in FIG. 9, needle-stick module **226** includes movable member **972**. When needle/catheter module **218** is inserted into haptics device **102**, needle **650** or catheter **758** couples to movable member **972**. The movable member is capable of moving forward or backward along translational axis **A-A**; for example, as a user manipulates needle/catheter module **218** into or out of haptics device **102**. In some embodiments, sensor **864A** monitors translational motion of movable member **972** and, hence, the translational motion of needle/catheter module **218**.

[0079] It is desirable for movable member **972** to move with very low friction. In some embodiments, this is implemented via an arrangement that provides "rolling

contact." In other words, to the extent that movable member **972** contacts a surface, the contact involves a rolling member (*e.g.*, pulleys against a cable, ball bearings against a surface, *etc.*) Rolling contact is to be distinguished, for example, from sliding contact, the latter typically associated with greater friction.

[0080] FIGs. 10A–10C, 11A–11D and 12 depict an embodiment of needle-stick module **226**. In particular, FIGs. 10A-10C depict an embodiment of needle-stick module **226** via exploded view (FIG. 10A), side view (FIG. 10B) and top view (FIG. 10C). FIGs. 11A-11D depict an illustrative embodiment of receiving module **1076**, which includes force-feedback assembly **862** and movable member **972**. And FIG. 12 depicts an illustrative embodiment of movable member **972**.

[0081] Referring now to the exploded view depicted in FIG. 10A, needle-stick module **226** comprises receiving module **1076**, base and gimbal assembly **1078**, and counterweight assembly **1080**. Receiving module **1076** couples to secondary-gimbal bracket **1083**, counterweight holder **1081** rigidly couples to pitch potentiometer shaft **1084**, and link **1086** couples, at one end, to receiving module **1076** (via to ball-joint ball **1090**) and at the other end to counterweight holder **1081** (*see also*, FIGs. 10B, 10C). Base **1079** of needle-stick module **226** is disposed on the bottom inside surface of housing **216** in the manner depicted in FIGs. 4A and 4B.

[0082] The illustrative embodiment of needle-stick module **226** provides three degrees of freedom—one translational and two rotational—as follows. Movable member **972** moves within receiving module **1076** along translational axis **1-1**. This provides the "translational" degree of freedom. (*See also*, FIG. 10C, translational movement is movement in the directions indicated by path **A-A**.) Secondary gimbal bracket **1083** and receiving module **1076** rotate about pitch axis **2-2**. (*See also*, FIG. 10B, pitch is movement in the directions indicated by path **B-B**.) Primary-gimbal bracket **1088** and receiving module **1076** rotate about yaw axis **3-3**. (*See also*, FIG. 10C, yaw is movement in the directions indicated by path **C-C**.) Rotation about the pitch and yaw axes provide the two "rotational" degrees of freedom of needle-stick module **226**.

[0083] In the illustrative embodiment, pitch and yaw of receiving module **1076** are tracked by potentiometers. More particularly, pitch is evaluated using pitch potentiometer **1092** and yaw is evaluated using yaw potentiometer **1094**, as

described further below. Potentiometers **1092** and **1094** are, therefore, specific embodiments of generic sensor(s) **864** of FIG. 8.

[0084] With continuing reference to FIG. 10A, pitch potentiometer **1092** is coupled to the obscured side of potentiometer holding plate **1096**. As receiving module **1076** swings up or down (*i.e.*, pitches), link **1086** forces counterweight holder **1081** to rotate about an axis that aligns with pitch potentiometer shaft **1084** (*see also*, FIG. 10B). Since counterweight holder **1081** is rigidly attached to potentiometer shaft **1084**, that shaft turns as the counterweight holder rotates. Rotation of the potentiometer shaft and, hence, pitching of receiving module **1076** is therefore "sensed" by pitch potentiometer **1092**. Pitch potentiometer **1092** is electrically coupled to electronics/communications interface **228** (not depicted in FIG. 10A, *see*, *e.g.*, FIGs. 4A and 4B). Pitch potentiometer **1092** generates a signal indicative of the sensed movement and transmits it to electronics/communications interface **228** and, through it, to data processing system **104**. It is notable that since counterweight **1082** moves along with counterweight holder **1081**, the weight of receiving module **1076** is counterbalanced through its full range of motion.

[0085] Still referring to FIG. 10A, yaw potentiometer **1094** is disposed beneath yaw potentiometer shaft **1097** and is coupled to an obscured surface of base **1079**. Primary-gimbal bracket **1088** is mechanically coupled to yaw potentiometer shaft **1097** by links **1098** and **1099** (*see also,* FIG. 10C). Yaw potentiometer shaft **1097** is coupled to yaw potentiometer **1094** in known fashion. Rotation of yaw potentiometer shaft **1097** and, hence, yawing of receiving module **1076** is therefore "sensed" by yaw potentiometer **1094**. The yaw potentiometer is electrically coupled to electronics/communications interface **228** (not depicted in FIG. 10A, *see*, *e.g.*, FIGs. 4A and 4B). Yaw potentiometer **1094** generates a signal indicative of the sensed movement and transmits it to electronics/communications interface **228** and, through it, to data processing system **104**. Potentiometers suitable for use as potentiometers **1092** and **1094** are commercially available from Clarostat Sensors and Controls, Inc. of El Paso, Texas, among others.

[0086] In use, the catheter and or needle of needle-catheter module **218** is inserted into guide **1089**. Once inserted into guide **1089**, the tip of the catheter or needle and movable member **972** couple to one another. In the illustrative embodiment, magnet **973** is disposed at the forward end of movable member **972**

(*see*, FIGs. 10A and 12). The magnet is used as a means to readily and reversibly couple the tip of needle **650** or catheter **758** to movable member **972**.

[0087] It was previously disclosed that in some embodiments, movable member **972** is coupled to a force-feedback system, referred to earlier as force-feedback assembly **862**. As previously described, force-feedback assembly **862** generates a resistance to continued insertion of needle-catheter module **218** into receiving module **1076**. An illustrative embodiment of force-feedback assembly **862** and additional description of receiving module **1076** is now provided in conjunction with FIGs. 11A-11D.

[0088] FIG. 11A depicts an exploded view of an embodiment of receiving module **1076**. In the illustrative embodiment, receiving module **1076** includes frame **1149**, which comprises lower plate **1150** and upper plate **1152**. The receiving module also includes movable member **972** and force-feedback assembly **862**, which comprises motor **1156**, motor encoder **1158**, motor pulley **1160**, pulleys **1162**, and cable **1164** (shown in FIG. 11D only).

[0089] Movable member **972** is disposed between upper and lower plates **1150** and **1152** and is positioned between centrally-located openings **1154** in the plates. Referring to FIG. 11B, movable member **972** is suspended at pulleys **1274A** and **1274B** (*see also*, FIG. 12) by cable **1164**, which is depicted as a dashed line for clarity. Cable **1164** is fixed at one end by holder **1166** and fixed at the other end by holder **1168**. Holders **1166** and **1168** are coupled to one another by tensioning screw **1170**, which adjusts the tension in cable **1164**. Cable **1164** is supported at a variety of intermediate locations by pulleys **1162** (*i.e.*, **1162A-1162D**). The cable also wraps around motor pulley **1160**, thereby coupling movable member **972** to motor **1156**.

[0090] FIGs. 11C and 11D depict a bottom view of receiving module **1076**. These Figures depicts sequential "snap shots," wherein needle **650**/catheter **758** is inserted deeper into receiving module **1076** (*e.g.*, by a user practicing a vascular-access technique with needle/catheter module **218**, *etc.*). Since the needle/catheter is coupled to movable member **972** (*e.g.*, by magnet **973**, *etc.*), the movable member is also moved "deeper" into receiving module **1076**. Indeed, once coupled, any movement of needle/catheter module **218** causes movable member **972** to advance or retreat along axis **1-1** within region **1154** of plates **1150** and **1152**.

[0091] As described above, motor **1156** is coupled to movable member **972** via cable **1164** (FIG. 11B). Any movement of the movable member therefore causes the motor to move. For example, as movable member **972** moves forward or "deeper" into receiving module **1076**, motor pulley **1160** turns in a clockwise direction (for the particular arrangement depicted in FIG. 11B). Movement of the motor pulley causes the motor to turn and this movement is captured by encoder **1158** (FIG. 11A) in known fashion. As a consequence, translational motion of movable member **972**, and, therefore, the position of needle/catheter module **218**, is sensed by encoder **1158**. The encoder is therefore an embodiment of sensor(s) **864** of FIG. 8. The encoder is electrically coupled to electronics/communications interface **228** (*see, e.g.*, FIGs. 4A and 4B). Encoder **1158** generates a signal indicative of the movement of motor **1156** and transmits it to electronics/communications interface **228** and, through it, to data processing system **104**.

[0092] In addition as functioning as a means for tracking the position of movable member **972** (and needle/catheter module **218**), motor **1156** also functions as a key element of force-feedback assembly **862**.

[0093] In particular, responsive to a control signal (*e.g.*, generated by controller **870** of FIG. 8, *etc.*), which is based on calculations performed by data processing system **104**, the motor engages with a specified amount of torque in a counterclockwise direction (for the particular arrangement depicted in FIG. 11B). This generates a force, F_R, which opposes or counters the force applied by a user during continued insertion of needle/catheter **218**. As previously described, force F_R is intended to simulate the resistance that would be presented by various anatomical features, were the simulated vascular-access procedure an actual procedure that was being performed on a real anatomy.

[0094] It is notable that in the arrangement that is depicted in FIG. 11B, the insertion force applied by a user is aligned with the tension in cable **1164** and with the translational degree of freedom. As a consequence, no unusual or unrealistic torque sensations are experienced by a user as needle/catheter module **218** is inserted into receiving module **1076**.

[0095] A motor suitable for use in conjunction with the present invention is a coreless brushed DC motor, such as is commercially available from Maxon Precision Motors, Inc. of Fall River, Massachusetts. In some embodiments, cable **1164** is

made from stainless steel and the pulleys **1162** are nylon pulleys. In such embodiments, the force-feedback assembly has very low inertia, very low friction, and is very stiff. As will be appreciated by those skilled in the art, these are all attributes of a good haptics design.

[0096] It is to be understood that the above-described embodiments are merely illustrative of the present invention and that many variations of the above-described embodiments can be devised by those skilled in the art without departing from the scope of the invention. For example, in this specification, numerous specific details are provided in order to provide a thorough description and understanding of the illustrative embodiments of the present invention. Those skilled in the art will recognize, however, that the invention can be practiced without one or more of those details, or with other methods, materials, components, *etc.*

[0097] Furthermore, in some instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the illustrative embodiments. It is understood that the various embodiments shown in the Figures are illustrative, and are not necessarily drawn to scale. Furthermore, the particular features, structures, materials, or characteristics can be combined in any suitable manner in one or more embodiments. It is therefore intended that such variations be included within the scope of the following claims and their equivalents.